IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

HEC PHARM CO., LTD., et al.,

Defendants.

C.A. 20-133-JLH (Consolidated)

[redacted]

PUBLIC VERSION FILED: September 12, 2025

CONCISE STATEMENT OF FACTS IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON NONINFRINGEMENT AND DATE OF HYPOTHETICAL NEGOTIATION AND DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF DR. CHRISTOPHER A. VELLTURO

Citation	Description
Novartis or Plaintiff	Novartis Pharmaceuticals Corporation
Defendants	HEC Pharm Co., Ltd., HEC Pharm Usa Inc. ("HEC"), Sunshine Lake Pharma Co., Ltd. ("Sunshine"), CANDA HEC-1, LLC ("CANDA"), and Rising Pharma Holdings, Inc. d/b/a Rising Pharmaceuticals, Inc. ("Rising")
Tren. Decl.	Declaration of Robert W. Trenchard in Support of Novartis's Motion for Partial Summary Judgment
Ex.	Tren Decl. Exhibit
S1P	Sphingosine-1-phosphate
VZV	Varicella zoster virus
RRMS	Relapse-remitting multiple sclerosis
DMT	Disease-modifying therapy
'179 Patent	U.S. Patent No. 10,543,179 (Ex. 1)
Pleasure Op. Rpt.	Opening Expert Report of Samuel Pleasure, M.D., Ph.D. on Invalidity of U.S. Patent No. 10,543,179, dated April 15, 2025 (Ex. 2)
Pleasure Reb. Rpt.	Rebuttal Expert Report Of Samuel Pleasure, M.D., Ph.D. On Non-Infringement Of U.S. Patent No. 10,543,179 (Ex. 3)
Pleasure Reply Rpt.	Reply Expert Report of Samuel Pleasure, M.D., Ph.D. on Invalidity of U.S. Patent No. 10,543,179, dated June 17, 2025 (Ex. 4)
Berger Op. R.	[Corrected] First Expert Report of Joseph R. Berger, M.D. regarding Infringement of U.S. Patent No. 10,543,179, dated April 16, 2025 (Ex. 5)
Berger Reply Rpt.	Reply Expert Report of Joseph R. Berger, M.D. regarding Infringement of U.S. Patent No. 10,543,179, dated June 17, 2025 (Ex. 6)
Lublin Op. Rpt.	First Expert Report of Fred D. Lublin, M.D., dated April 15, 2025 (Ex. 7)
Vellturo Op. Rpt.	Expert Report of Christopher A. Vellturo, Ph.D., dated April 15, 2025 (Ex. 8)
Steinman Reb. Rpt.	First Expert Report of Lawrence Steinman, M.D. regarding Validity of U.S. Patent No. 10,543,179, dated May 20, 2025 (Ex. 9)
Collins Decl.	Declaration of William Collins, dated July 9, 2019 (NPCFINGO012724847) (Part of '179 Patent File History) (Ex. 10)
2/11/2025 Baeringer Dep. Tr.	Deposition Transcript of Ira Baeringer, dated Feb. 11, 2025 (Ex. 11)
1/30/2025 Harris Dep. Tr.	Deposition Transcript of Joshua Harris, dated Jan. 30, 2025, 2025 (Ex. 12)

Citation	Description
1/9/2025 Bischof Dep. Tr.	Deposition Transcript of Dorina Bischof, dated Jan. 9, 2025 (Ex. 13)
8/25/2022 Burtin Dep. Tr.	Deposition Transcript of Pascale Burtin, dated Aug. 25, 2022 (Ex. 14)
9/23/2022 Boulton Dep. Tr.	Deposition Transcript of Craig Boulton, dated Sept. 23, 2022 (Ex. 15)
10/21/2022 Schmouder Dep. Tr.	Deposition Transcript of Robert Schmouder, dated Oct. 21, 2022 (Ex. 16)
10/14/20022 Dumortier Dep. Tr.	Deposition Transcript of Thomas Dumortier, dated Oct. 14, 2022, 2025 (Ex. 17)
9/16/2022 Hunt Dep. Tr.	Deposition Transcript of Irene Hunt, dated Sept. 16, 2025 (Ex. 18)
7/14/2025 Pleasure Dep. Tr.	Deposition Transcript of Samuel Pleasure, dated July 14, 2025 (Ex. 19)
7/10/2025 Berger Dep. Tr.	Deposition Transcript of Joseph Berger, dated July 10, 2025 (Ex. 20)
Final Invalidity Contentions	HEC's Invalidity Contentions, dated June 24, 2022 (Ex. 21)
October 2024 Defendants' Label	Defendants' Fingolimod Label, October 2024 (HECFINGO00126295) (Ex. 22)
Side-by-Side Comparison of June 2024 Gilenya® Label and October 2024 Defendants' Label	Defendants' ANDA 207939 Annex 1 Side-by-side comparison of proposed labeling and last submitted labeling (HECFINGO00126347) (Ex. 23)
NMSS 2025	NPCFINGO012725237 (Ex. 24)

A. U.S. Patent No. 10,543,179 ("the '179 patent"); B. HEC's ANDA, its Label, and Commercial Marketing of its Generic Fingolimod.

1-7. Admitted.

C. Treatment of MS Patients and Administration of VZV Vaccines.

8-13. Admitted.

14. Disputed. Some DMTs do not broadly suppress the immune system and thus are more accurately characterized as "immunomodulatory." Fingolimod is an example: "by modulating these S1P receptors, fingolimod has a powerful immunomodulating effect, causing sequestration of lymphocytes in the peripheral lymph nodes." (D.I. 393-1, Ex. C (Steinman Reb. Rpt.) ¶ 75; *see also* D.I. 393-16, Ex. EEEE (Berger Op. R.) ¶¶ 5, 32–33.)

15. Disputed. Persons with compromised immune systems may be more susceptible to VZV infection, but beyond that, the breadth of Defendants' proposition is disputed. (D.I. 393-1, Ex. C (Steinman Reb. Rpt.) ¶ 55; *id.* at¶ 99 ("None of the advisors raised any concern regarding infection risk [from Fingolimod], including from VZV.");

16. Disputed. The "standard protocol" referenced by Defendants is the invention claimed in the '179 Patent and introduced with Novartis's Gilenya label. (D.I. 392-1. Ex. 7 (Lublin Op. R.) ¶ 10–11; D.I. 392-2–392-4, Ex. 23 (Label Comparison); D.I. 393-1, Ex. A ('179 Patent) Cls. 1–4.) Since that time, the protocol has been applied to other MS treatments. (D.I. 386-1, Ex. P (Berger Reply R.) ¶ 30 ("six out of all currently available MS DMTs require VZV screening and vaccination"); D.I. 393-16, Ex. EEEE (Berger Op. R.) ¶ 45.) None of Defendants' cited sources stand for the proposition that the claimed protocol existed at or before the conception of the '179 Patent's safety protocol from any other source or for any other MS treatment. (D.I. 393-16, Ex. EEEE (Berger Op. R.) ¶¶ 44–45); D.I. 393-1, Ex. C (Steinman Reb. R.) ¶ 171.) Defendants' statements ignore the plain language of the claims that testing and vaccination are for the purpose

of "treating [RRMS] in a patient." (D.I. 393-1, Ex. A ('179 Patent) Cl. 1.)

17. Disputed. This is not true of all DMTs. For example, Betaseron, Avonex, Copaxone, Mitoxantrone, and Tysabri do not include this in their protocol. (D.I. 393-1, Ex. C (Steinman Reb. R.) ¶¶ 63–67.) Defendants' citations do not support their assertion.

18. Disputed. The passage cited by Defendants does not mention "a patient" who "refused to have a vaccination" or that "the physician would not withhold MS treatment" from that patient. Nor does it mention that "should a patient develop zoster while on a DMT, the patient can be treated with varicella zoster immune globulin." Instead, Dr. Lublin explained that "immunoglobulin" can be given to "a patient who is receiving immunosuppressive treatment and is exposed to VZV" and confirmed it is not the "only way to achieve protection against VZV infection." (D.I. 393-16. Ex. DDDD (Lublin Dep. Tr.) 223:7–25.) With respect to "not withholding MS treatment," Dr. Lublin is clear that he would not refuse to treat someone generally. (D.I. 386-1, Ex. M (Lublin Reply R.) ¶ 17 ("I did not suggest in my opening report that I would refuse entirely to treat a patient that refused vaccination—that is not the case.")

19. Disputed. It is not clear what Defendants mean by "at risk of VZV infection." But from the doctor's perspective, anyone who tests negative for VZV antibodies is "at risk," even if they in fact have immunity (e.g., from vaccination) because there is no way to determine that immunity. According to Dr. Berger, it is around 90%, noting documented errors in the relevant studies and a ramp up period in vaccination corresponding to discrepancies in year cohorts. Other evidence places the percentage at around 95%. Doctors determine risk from confirmed medical records and from serological testing, and based on the available information, there is still dispute. At bottom, however, it is undisputed that 25% of Defendants' fingolimod sales are used to practice the claimed safety protocol. The label recommends that doctors identify "a patient at risk of

contracting infection" by testing RRMS patients for VZV antibodies, and then vaccinating any VZV-seronegative patients before administering the drug. (D.I. 408-, Ex. 7 (Lublin Op. R.) ¶¶ 101–120.) Dr. Berger explains that this VZV protocol has been adopted at many prominent MS centers and groups, such as the Cleveland Clinic Mellen Center for MS, the University of Pennsylvania, the National MS Society, the Veterans Affairs MS Center, and Kaiser Permanente. (D.I. 408, Ex. 5 (Berger Op. R.) ¶¶ 34, 56–62.). Dr. Berger himself has practiced the protocol on "hundreds" of patients. (D.I. 408, Ex. 20 (7/10/2025 Berger Dep. Tr.) 170:6–17.) [redacted] Of these, contemporary literature on the rate of negative tests for VZV antibodies predicts that as many as one-third would test negative and thus be vaccinated; but to be conservative, [redacted]

20. Disputed. As explained in response to Paragraph 19, it is undisputed that [redacted]

21. Disputed. Dr. Lublin explained that there are instances where a patient would be re-tested. (D.I. 393-16. Ex. DDDD (Lublin Dep. Tr.) 167:4–168:21.)

22. Disputed. While there are not direct tests, this number can be accurately estimated. (D.I. 393-16, Ex. EEEE (Berger Op. R.) ¶ 70.) As set forth in response to Paragraph 19, Dr. Berger proved that here.

23. Disputed. Defendants' citations point to the experience of one doctor, Dr. Lublin,

not the entire field. And Dr. Lublin explains that the labels and onboarding processes are the same for Gilenya and Defendants' fingolimod product. For example, in his opening report, Dr. Lublin says that doctors read "the label." (D.I. 408-, Ex. 7 (Lublin Op. Rpt.) ¶ 4.) He further notes that: "Having read the label, neurologists would be highly likely to follow this protocol." (D.I. 408-, Ex. 7 (Lublin Op. Rpt.) ¶ 7.) In his reply report when discussing infringement, Dr. Lublin emphasized that the statements in his opening report were in reference to Defendants' label. (D.I. 386-1, Ex. M (Lublin Reply R.) ¶ 12.) And he also says "Doctors follow these labels, which have been vetted by the FDA and supported with rigorous clinical trial data, as shown above." (*Id.* ¶ 106.) And ". . . a doctor reading the label would follow its instructions . . . " (*Id.*) Dr. Lublin says clearly that doctors are aware of and rely on the contents in Defendants' label. (*Id.* ¶¶ 3, 13.) And he confirms that doctors take the label instructions seriously. (*Id.* ¶ 18.) Dr. Berger agrees. (D.I. 393-16, Ex. EEEE (Berger Op. R.) ¶¶ 81, 84, 85.)

24. Disputed. Defendants' cited references do not show that protocols "were not modified upon the release or availability of generic fingolimod." At a minimum, as the generic products were released, those generic product labels were confirmed to be identical such that the protocols did not require modification. In other words, the protocols, if unmodified, are only unmodified *because* Defendants' label copied the Gilenya label. If Defendants' label had different safety instructions, there would have to be a change to those protocols. Dr. Berger also confirmed that the pharmacist reviews test results as part of the process, working at his direction. (D.I. 408, Ex. 20 (7/10/2025 Berger Dep. Tr.) 158:10-162:3.)

25. Disputed. Drs. Berger and Lublin confirm that they might know which version a patient ultimately got, even if they did not make the call. (D.I. 393-16. Ex. DDDD (Lublin Dep. Tr.) 164:4-25). Generic fingolimod would not be allowed without the same label, and physicians

are relying on that label criteria to proscribe fingolimod. It does not matter if the pharmacist or insurance company ultimately decides which generic (or the branded version) patients get. Defendants' statement is an overgeneralization of their cited testimony. For example, physicians can dispense as written.

26. Disputed for the reasons set forth in response to Paragraph 25.

27. Disputed for the reasons set forth in response to Paragraph 25. Further, the cited language only stands for the proposition that physicians test for VZV according to the label.

28. Disputed for the reasons set forth in response to Paragraph 25.

29. Disputed. Dr. Lublin explained fingolimod is not *his* first choice of MS treatment. Dr. Lublin never offered an opinion as to other physicians. Further, Defendants' do not specify a timeframe. At certain instances in time, fingolimod was the first choice. D.I. 392-1. Ex. 7 (Lublin Op. R.)

D. Novartis' Infringement Allegations and Lack of Evidence Supporting Any Direct Infringement.

30. Disputed. Novartis alleges infringement under both 35 U.S.C. §§ 271(e) and (b). (D.I. 367 at 8–12.)

31. Disputed. Novartis's allegations depend on many types of evidence, including, *inter alia*, documents produced by Defendants, testimony from the experts and fact witnesses, and public data. (*See e.g.*, D.I. 393-16, Ex. EEEE (Berger Op. R.)) And more broadly, Novartis relies on the fact that there has been copious amounts of direct infringement even since Defendants' launch.

32-33. Disputed for the reasons set forth in response to Paragraph 19.

34. Disputed for the reasons set forth in response to Paragraph 19. In addition, Defendants' fingolimod product could not be sold at all without the label. And, for the reasons set

forth in response to Paragraph 23, physicians are at least aware of Defendant's label and rely on the fact that it is a copy of the Gilenya label.

35. Disputed. Defendants improperly broaden the sources they cite. The cited paragraph in Novartis's First Amended Complaint is on information and belief with respect to Gilenya only. (D.I. 367, ¶ 44) Exhibit 3 to Dr. Vellturo's report depicts Novartis's Gilenya net sales and patient assistance expenses. (D.I. 386-2, Ex. T at Ex. 3). Exhibit 5 sets forth Defendants' fingolimod product monthly actual sales and net price. (*Id.* at Ex. 5.) And Exhibit 6 sets forth monthly fingolimod U.S. IQVIA-estimated unit sales shares by supplier and estimate of Novartis but-for share (proportional allocation). (*Id.* at Ex. 6.) None explicitly set forth Defendants' proposition.

36. Disputed for the reasons set forth in response to Paragraphs 16, 17, 19, 21 and 29. Defendants further provide no support for this assertion with respect to all time periods at issue.

37. Disputed for the reasons set forth in response to Paragraph 36. Further, any such patient would at most have been tested and vaccinated with some DMT products, such as S1Ps. (D.I. 393-16, Ex. EEEE (Berger Op. R.) ¶ 58.)And even then, it would depend on when they started on the drug; the protocol was not in place for other DMTs prior to the invention of the '179 Patent and its inclusion on the Gilenya label. (*Id.* ¶¶ 44–45); D.I. 393-1, Ex. C (Steinman Reb. R.) ¶ 171.)

38. Disputed for the reasons set forth in response to Paragraph 19.

39. Disputed for the reasons set forth in response to Paragraph 21. Further, this assertion is disputed in as much as the prior vaccination was unrecorded in available medical records and/or the patient still tests negative serologically. (D.I. 386-1, Ex. P (Berger Reply R.) ¶¶ 32–33; D.I. 393-16, Ex. EEEE (Berger Op. R.) ¶ 65.)

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CERTIFICATE OF SERVICE

The undersigned counsel certifies that true and correct copies of the foregoing document were caused to be served on August 28, 2025 on the following counsel in the manner indicated:

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